

REMARKS

A. BACKGROUND

The present Amendment is in response to the Office Action mailed January 2, 2009. Claims 11-16, 21-25, 27-32, 38-42, 46-51, 54-56, 60-75 and 81-90 were pending and rejected in view of cited art.¹ Claims 32, 50, and 73 are canceled and claims 11, 21, 27, 40, 47, 61, 63, and 68 are amended. Claims 11-16, 21-25, 27-31, 38-42, 46-49, 51, 54-56, 60-72, 74-75, and 81-90 are now pending in view of the above amendments.²

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, is consistent with the Examiner's understanding.

B. EXAMINER'S INTERVIEW

Applicant's express their appreciation to the Examiner for conducting an interview with Applicant's representative on April 13, 2009. The substance of the interview is included in this response.

¹ Although the prior art status of the cited art is not being challenged at this time, Applicant reserves the right to challenge the prior art status of the cited art at any appropriate time, should the need arise. Accordingly, any arguments and amendments made herein should not be construed as acquiescing to any prior art status of the cited art.

² Support for the claim amendments and/or new claim(s) can be found throughout the specification and/or drawings as originally filed.

C. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

The Office Action rejected claims 61-62 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In response, the dependency of claim 61 has been changed so that claim 61 depends from claim 51. Accordingly, Applicant respectfully requests withdrawal of the rejection under Section 112.

D. PRIOR ART REJECTIONS

I. REJECTION UNDER 35 U.S.C. § 103

The Office Action rejected claims 11-16, 21-25, 27-32, 38-42, 46-49, 51, 54-56, 60-75 and 81-90 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,853,421 (*Leschinsky*) in view of U.S. Patent No. 6,626,918 (*Ginn 1*) or U.S. Patent No. 6,391,048 (*Ginn 2*). Claim 50 was rejected under 35 U.S.C. § 103(a) as being unpatentable over *Leschinsky* in view of *Ginn 1* or *Ginn 2* and further in view of U.S. Patent No. 5,437,631 (*Janzen*).

Applicant traverses the Examiner's rejection for obviousness on the grounds that the references – either individually or in combination – fail to teach or suggest each and every element of the rejected claims. By contrast to the teaching of *Leschinsky*, independent claims 11, 21, 27, 40, 47, 63, 68 recite, in part, "a control element fixedly connected to" "the distal portion of" or "the distal end of" "the deflectable element" or "the helically wound wire."

Leschinsky was cited as disclosing "an apparatus for positioning a closure device within a passage, comprising: . . . a control element (12 for the first embodiment, for the 2nd embodiment there are more than one control member which are 212, 228, 238) coupled to the deflectable element extending along an outer surface of at least one coil," (Office Action, p. 3). With respect to the first embodiment, *Leschinsky* mentions that "the sheath can be caused to buckle or form a bulge or notch 18 leaving a gap 20 between the core wire and the slit portion of the sheath which forms notch 18," (col. 5, ll. 8-11). However, Applicant has been unable to find in *Leschinsky* of any teaching or suggestion of how the sheath is buckled. It does not appear that the core wire is movable to buckle the sheath.

For one configuration, as illustrated in FIG. 1, *Leschinsky* indicates that the core wire 12 can "slide through sheath 14 until its distal tip is proximal notch 18, thus releasing loop 24, permitting the distal end of sheath 14 to become flaccid (*see* FIG. 16) and enabling sheath 14 to

be with withdrawn entirely from collagen plug 68," (col. 7, ll. 54-58). Applicant has been unable to find any teaching that the core wire is movable proximally to buckle the sheath or that the control element extends from the distal portion to the proximal end of the expandable locator. Rather, movement of the core wire 12 allows the release of loop 24. Further, because the distal tip is slid through until it is proximal the notch, Applicant respectfully submits that the core wire 12 is not fixedly connected to the distal end of the deflectable element.

In another configuration, with respect to FIG. 19, *Leschinsky* indicates that "[a]lthough the manner of forming the loop . . . is somewhat different from that of the first version, the end result is substantially the same," (col. 8, ll. 15-17). The loop is formed by pulling "an intermediate portion of core wire 12, near its distal end . . . out of the slit," (col. 8, ll. 6-8). "To release the anchor . . . , the core wire 12 is pulled in the direction of arrow R. This causes loop 84 to get smaller and smaller until that section of core wire reenters the slit (*see* FIG. 21) permitting easy withdrawal of wire 10," (col. 8, ll. 20-24). Applicant has been unable to find any teaching in *Leschinsky* that the core wire 12 is fixed to the distal end of the wire 10 or that the control element extends from the distal portion to the proximal end of the expandable locator. Further, Applicant has been unable to find any teaching that the core wire 12 is movable proximally to buckle sheath 14 when the core wire 12 is movable to reenter the slit. Rather, FIGs. 20 and 21 appear to illustrate the end of sheath 14 being in generally the same configuration prior to and after withdrawing of the core wire 12.

In still another configuration, with respect to FIG. 22, as with the configuration of FIG. 1 a gap is formed to receive a portion of the wire. Applicant has been unable to find in *Leschinsky* any teaching or suggestion of how the sheath is buckled. It does not appear that the core wire is movable to buckle the sheath. In addition, the core wire 12 movable to open the notch does not appear to be fixed to the distal end of the sheath, because the distal end has to be withdrawn so that its distal tip is proximal notch 18.

With respect to the second embodiment, it is indicated that "for the 2nd embodiment there are more than one control member which are 212, 228, 238) coupled to the deflectable element," (Office Action, p. 3). As illustrated in FIG. 28, the core wire 212 terminates proximal the distal end and wire barb 228 attaches to the core wire 212. The split sleeve 238 is disposed at the proximal rather than the distal end (*See* FIG. 29). Applicant respectfully submits, therefore, that elements 212, 228, and 238 do not appear to be fixed to the distal portion of the deflectable

element identified in the Office Action or that the control element extends from the distal portion to the proximal end of the expandable locator.

In addition, the Office Action indicates that "the control element being movable axially for causing an intermediate portion of the deflectable element to buckle substantially transversely with respect to the longitudinal axis (Fig. 1-3 and 28-29) . . .," (Office Action, p. 3). However, *Leschinsky* teaches that "[a]t the proximal end of the insertion guide wire 210, core wire 212 extends beyond the proximal end 236 of core wire sheath 214 (Fig. 29). Core wire then passes through split sleeve 238 and the proximal end 240 of core wire 214 is affixed . . . to a short section of proximal coil 242," (col. 11, ll. 11-17)(emphasis added). "[C]ontinued force applied to coil 242 [i.e., proximal coil] causes split sleeve 238 [i.e., proximal split sleeve] to buckle and separate along slit 246 [disposed at the proximal end] thereby permitting core wire 212 to move distally within core wire sheath 214," (col. 11, ll. 45-48). Applicant has been unable to find any teaching in *Leschinsky* of a distal portion of the insertion wire buckling "substantially transversely with respect to the longitudinal axis", rather the identified buckling occurs at the proximal end.

In view of the above, Applicant respectfully submits that *Leschinsky* neither teaches nor suggests "a control element fixedly connected to" "the distal portion of" or "the distal end of" "the deflectable element" or "the helically wound wire," as recited, in part, in independent claims 11, 21, 27, 40, 47, 63, 68. Further, *Leschinsky* neither teaches nor suggests a "control element extending from a distal portion to the proximal end of the locator member and being movable axially to buckle an intermediate portion of the deflectable element substantially transversely with respect to the longitudinal axis" as recited, in part, in independent claims 11 and 63, "moving a control element . . . to buckle the deflectable element on the distal portion of the selectively expandable locator member from an axial collapsed configuration to a transverse expanded configuration," as recited, in part, in independent claim 27, "moving a control element . . . to buckle the deflectable element of the distal portion of the selectively expandable locator member from a collapsed configuration to a transversely expanded configuration within the body lumen", as recited, in part, in independent claims 40 and 47, or "moving a control element . . . to buckle the deflectable element comprising a helically wound wire on the distal portion of the locator member from an axial collapsed configuration to a transverse expanded configuration" as recited, in part, in independent claim 68. In addition to the above, Applicant respectfully submits that *Leschinsky* neither teaches nor suggests "the control element extending from the distal

portion to the proximal end of the expandable locator member and between a first pair of adjacent uniform coils of the helical wound wire and along an outer surface of at least one coil of the helical wound wire and passing between a second pair of adjacent uniform coils of the helical wound wire in a pre-deployed configuration."

Ginn 1 and *Ginn 2* were cited as disclosing a clip, while *Janzen* was cited for disclosing "that introducing one or more instruments through the lumen of a tubular member (32) into the body lumen prior to performing the closure of the blood vessel" (Office Action, pg. 12). Applicant respectfully submits that *Ginn 1*, *Ginn 2*, and *Janzen*, either alone or in combination, do not appear to overcome the deficiencies of *Leschinsky*.

In view of this, Applicant submits that *Leschinsky*, *Ginn 1*, *Ginn 2*, or *Janzen*, whether alone or in combination, neither teach nor suggest the inventions claimed in independent claims 1, 21, 27, 40, 47, 63, 68. Applicant also respectfully submits that dependent claims 11-16, 22-25, 28-32, 38-39, 41, 42, 46, 48-51, 54-56, 60-62, 64-67, 69-75 and 81-90 are not rendered obvious by *Leschinsky*, *Ginn 1*, *Ginn 2*, or *Janzen*. As such, Applicant respectfully requests that the rejection of claims 12-16, 21-25, 27-32, 38-42, 46-51, 54-56, 60-75 and 81-90 under Section 103 be withdrawn.

E. CONCLUSION

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.

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For at least the foregoing reasons, Applicant respectfully submits that the pending claims are neither anticipated by nor made obvious by the art of record. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 4th day of May, 2009.

Respectfully submitted,

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